

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval Washington Medicaid State Plan Amendment (SPA) 17-0002

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of hearing; reconsideration of disapproval.

SUMMARY: This notice announces an administrative hearing to be held on January 15, 2019, at the Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Medicaid and Children's Health, Seattle Regional Office, 701 Fifth Avenue, Suite 1600, Seattle, WA 98104 to reconsider CMS' decision to disapprove Washington's Medicaid SPA 17-0002.

DATES: Requests to participate in the hearing as a party must be received by the presiding officer by December 20, 2018.

FOR FURTHER INFORMATION CONTACT: Benjamin R. Cohen, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244, Telephone: (410) 786-3169.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS' decision to disapprove Washington's Medicaid state plan amendment (SPA) 17-0002, which was submitted to the Centers for Medicare & Medicaid Services (CMS) on June 26, 2017 and disapproved on September 10, 2018. This SPA requested CMS approval to: Bring Washington into compliance with the pharmacy reimbursement requirements in the Covered Outpatient Drugs final rule with comment period (CMS-2345-FC) (Final Rule). Specifically, SPA 17-0002 proposed to revise the current pharmacy reimbursement methodology from reimbursing for ingredient costs based on Estimated Acquisition Cost (EAC), plus a tiered dispensing fee (High-volume pharmacies \$4.24/Rx, Mid-volume pharmacies \$4.56/Rx, Low-volume pharmacies \$5.25/Rx, and Unit Does System \$5.25/Rx), to reimbursing for ingredient cost based on Actual

Acquisition Cost (AAC), using the National Average Drug Acquisition Cost (NADAC) without a change in the new requirements for a professional dispensing fee. In addition, SPA 17-0002 included proposed changes to reimbursement for 340B drugs, physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price.

The issues to be considered at the hearing are whether Washington SPA 17-0002 is inconsistent with the requirements of:

- Section 1902(a)(30)(A) of the Social Security Act (the Act) which requires, in part, that states have a state plan that provides such methods and procedures to assure that payment rates are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

- Federal regulations at 42 CFR 447.502, 447.512 and 447.518 which provide that payments for drugs are to be based on the ingredient cost of the drug based on AAC and a Professional Dispensing Fee (PDF).

Section 1116 of the Act and federal regulations at 42 CFR part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. CMS is required to publish in the **Federal Register** a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the state Medicaid agency of additional issues that will be considered at the hearing, we will also publish that notice in the **Federal Register**.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Washington announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. MaryAnne Lindeblad

Director
State of Washington, Health Care Authority
626 8th Avenue PO Box 45502
Olympia, WA 98504-5050

Dear Ms. Lindeblad:

I am responding to your November 5, 2018 request for reconsideration of the decision to disapprove Washington's State Plan amendment (SPA) 17-0002. Washington SPA 17-0002 was submitted to the Centers for Medicare & Medicaid Services (CMS) on June 26, 2017, and disapproved on September 10, 2018. I am scheduling a hearing on your request for reconsideration to be held on January 15, 2019, at the Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Medicaid and Children's Health, Seattle Regional Office, 701 Fifth Avenue, Suite 1600, Seattle, WA 98104.

I am designating Mr. Benjamin R. Cohen as the presiding officer. If these arrangements present any problems, please contact Mr. Cohen at (410) 786-3169. In order to facilitate any communication that may be necessary between the parties prior to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. If the hearing date is not acceptable, Mr. Cohen can set another date mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR part 430.

This SPA requested CMS approval to bring Washington into compliance with the pharmacy reimbursement requirements in the Covered Outpatient Drugs final rule with comment period (CMS-2345-FC) (Final Rule). Specifically, SPA 17-0002 proposed to revise the current pharmacy reimbursement methodology from reimbursing for ingredient costs based on Estimated Acquisition Cost (EAC), plus a tiered dispensing fee (High-volume pharmacies \$4.24/Rx, Mid-volume pharmacies \$4.56/Rx, Low-volume pharmacies \$5.25/Rx, and Unit Does System \$5.25/Rx), to reimbursing for ingredient cost based on Actual Acquisition Cost (AAC), using the National Average Drug Acquisition Cost (NADAC) without a change in the new requirements for a professional dispensing fee. In addition, SPA 17-0002 included proposed changes to reimbursement for 340B drugs, physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price.

The issues to be considered at the hearing are whether Washington SPA 17-0027 is inconsistent with the requirements of:

- Section 1902(a)(30)(A) of the Social Security Act (the Act) which requires, in part, that states have a state plan that provides such methods and procedures to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.
- Federal regulations at 42 CFR 447.502, 447.512 and 447.518 which provide that payments for drugs are to be based on the ingredient cost of the drug based on AAC and a Professional Dispensing Fee (PDF).

In the event that CMS and the State come to agreement on resolution of the issues which formed the basis for disapproval, this SPA may be moved to approval prior to the scheduled hearing. Sincerely,

Seema Verma
Administrator
cc: Benjamin R. Cohen

Section 1116 of the Social Security Act (42 U.S.C. 1316; 42 CFR 430.18) (Catalog of Federal Domestic Assistance program No. 13.714. Medicaid Assistance Program.)

Dated: November 30, 2018.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.
[FR Doc. 2018-26495 Filed 12-4-18; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Plan for Foster Care and Adoption Assistance: Title IV-E of the Social Security Act.

OMB No.: 0970-0433.

Description: A title IV-E plan is required by section 471, part IV-E of the

Social Security Act (the Act) for each public child welfare agency requesting Federal funding for foster care, adoption assistance and guardianship assistance under the Act. Section 479B of the Act provides for an Indian tribe, tribal organization or tribal consortium (Tribe) to operate a title IV-E program in the same manner as a State with minimal exceptions. The Tribe must have an approved title IV-E Plan. The title IV-E plan provides assurances the programs will be administered in conformity with the specific requirements stipulated in title IV-E. The plan must include all applicable State or Tribal statutory, regulatory, or policy references and citations for each requirement as well as supporting documentation. A title IV-E agency may use the pre-print format prepared by the Children’s Bureau of the Administration for Children and Families or a different format, on the condition that the format used includes all of the title IV-E plan requirements of the law.

Respondents: Title IV-E agencies administering or supervising the administration of the title IV-E programs.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV-E Plan	17	1	16	272

Estimated Total Annual Burden Hours: 272.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. *Email address:* infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office

of Management and Budget, Paperwork Reduction Project, *Email:* OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
[FR Doc. 2018-26416 Filed 12-4-18; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: OCSE-157 Child Support Enforcement Program Annual Data Report

OMB No.: 0970-0177.

Description: The information obtained from this form will be used to: (1) Report Child Support Enforcement activities to the Congress as required by law; (2) calculate incentive measures performance and performance indicators utilized in the program; and (3) assist the Office of Child Support Enforcement (OCSE) in monitoring and evaluating State Child Support programs.

OCSE is proposing updates to the OCSE-157 report instructions to update and clarify reporting requirements. Respondents are encouraged to contact the agency to obtain a copy of the revised instructions for review and comment.

Respondents: State, Local or Tribal Government.